REMARKS

Applicants have carefully studied the outstanding Office Action. The present response is intended to be fully responsive to all points of rejection and/or objection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested. Applicants respectfully requests withdrawal of the Examiner's rejections in view of the following remarks.

CLAIM REJECTIONS – 35 U.S.C. § 102

The Examiner has rejected claims 1-4, 6-7, 9-10, 13, 15-21, 23, 25-28, 30-31, 34-38, 40, 42, 46-50, 52, 55, and 57 under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 5,698,090 issued to Bene et al. (hereinafter "Bene ").

Regarding independent claims 1, 25, and 42, the Examiner has specifically stated:

> Regarding claims 1, 25, 42 Bene et al. discloses a first pump (See Figure 1 (12)) that is configurable to pump a first metered (See Column 3 Lines 57-67, Column 4 Lines 1-13, 59-67, Column 5 Lines 1-8) amount of a first fluid through a first delivery line (See Figure 1 (11)) to a catheter (See Figure 1 (Between (8) and (9))); a second (See Figure 1 (22)) pump that is configurable to pump a second metered (See Column 3 Lines 57-67, Column 4 Lines 1-67, Column 5 Lines 1-17) amount of a second fluid through a second delivery line (See Figure 1 (21)), separate from said first delivery line, to said catheter (See Figure 1 (Between (8) and (9))); a processor (See Figure 1 (25)), connected to control said first and second pumps such that said second metered amount has a definable relationship to said first metered amount (See Column 3 Lines 57-67, Column 4 Lines 1-13, 59-67, Column 5 Lines 1-17); wherein the lumen of said first delivery line and the lumen of said second delivery line remain separate up to a connection point (See Figure 1 (8)) of said first and second delivery lines to said catheter.

We submit that Bene fails to teach each and every limitation of the claimed invention. Specifically, Bene fails to teach the following:

> Claim 1: "[a clinical fluid pumping system] wherein the lumen of said first delivery line and the lumen of said second delivery line remain separate up to a **connection point** of said first and second delivery lines to said catheter." (emphasis added)
>
> Claim 25: "[a clinical fluid pumping system] wherein said first delivery line and said second delivery line prevent the co-mingling of the first fluid and the second fluid up to a **connection point** of said first and second delivery lines to a catheter." (emphasis added)
>
> Claim 42: "[a method of providing a therapeutic agent to a targeted portion of the vascular system of a patient] wherein the first fluid in said first delivery line and the second fluid in said second delivery line are **not co-mingled at least until delivery into said catheter**." (emphasis added)

The Examiner is mistaken because Bene fails to teach that the first delivery line and the second delivery line remain separate up to a connection point. In fact, Bene teaches the use of a bubble trap (See Figure 1 (8)) as a means for combining the fluid in the first delivery line (21) with the fluid in the second delivery line (11). The limitation of a "connection point" as recited in the claims above is patently distinguishable from the bubble trap taught in Bene.

The terms "connection" and "point", having not been given any special definition in the specification of the application, must be given their plain meaning. *In re Zletz*, 893 F.2d 319, 321, 13 U.S.P.Q.2d 1320, 1322 (Fed. Cir. 1989). The term "connection" is defined by *Webster's New Universal Unabridged Dictionary* as "A state of being knit or fastened together". *Webster's* defines the term "point" as "Something thought of as having definite position in space, but no size or shape". In contrast, Bene teaches that the delivery lines are to be connected to a bubble trap at various different points on said bubble trap. The bubble trap, having a size and shape, is patently distinguishable from that which is recited in the claims above.

Furthermore, the bubble trap is patently distinguishable from present claims because the bubble trap acts to delay the flow of the fluids into the patient. The bubble trap's purpose is to ensure that air bubbles inadvertently introduced to the respective fluids are removed before entering the patient. The amount of time the fluids remain in the bubble trap will vary upon the configuration of said bubble trap. The connection point recited in the claims produces no such delay, thus preventing degradation of the fluids. A rejection under §102 for anticipation requires that the single reference teach each and every element or step of the rejected claim. *See, Atlas Powder v. E.I. DuPont*, 750 F.2d 1569, 224 U.S.P.Q. 409 (Fed. Cir. 1984). Therefore, Bene fails to anticipate the Applicants' claims.

Bene also fails to teach the following,

Claim 1: "A clinical fluid pumping system comprising: a first pump that is configurable to pump a first metered amount of a first fluid through a first delivery line **to a catheter** ... a second pump that is configurable to pump a second metered amount of a second fluid through a second delivery line, separate from said first delivery line, **to said catheter**." (emphasis added)

Claim 25: "[a clinical fluid pumping system] wherein said first delivery line and said second delivery line prevent the co-mingling of the first fluid and the second fluid up to a connection point of **said first and second delivery lines to a catheter**." (emphasis added)

Claim 42: "A method of providing a therapeutic agent to a targeted portion of the vascular system of a patient, said method comprising the steps of: ...pumping the first fluid at a measured rate to a first delivery line **attached to a catheter**. ... metering a given amount of a second fluid to a second delivery line for delivery **to said catheter**..." (emphasis added)

As previously stated, Bene teaches pumps that are configured to pump various fluids through first and second delivery lines to a bubble trap. Bene teaches that the

bubble trap is connected to a catheter. The claims of the present invention are patentably distinguishable from that which is disclosed in Bene because the claims of the present invention recite the limitation that the pumps are configured to pump their respective fluids to a catheter, as opposed to a bubble trap. Claim 42 explicitly recites the limitation that the first delivery line is attached to a catheter, both delivery lines in Bene being attached to the bubble trap. A prior art reference anticipates the claimed invention under 35 U.S.C. § 102 only if every element of a claimed invention is identically shown in that single reference, arranged as they are in the claims. *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). Examiner's rejection under § 102 fails to meet this test.

Various dependent claims have been rejected as anticipated by Bene et al. as well. Each of said claims depends on one of independent claims 1, 25, or 42. Therefore, the rejections of the various dependent claims below all share the weaknesses inherited with respect to the rejection of the independent claims above.

CLAIM REJECTIONS – 35 U.S.C. § 103

Claims 5, 8, 11-12, 14, 22, 24, 29, 32, 33, 39, 41, 43-44, 45, 51, 53-54, 56, and 58 are rejected under 35 U.S.C. §103 over Bene et al., either alone or in combination with another patent. It is submitted that these rejections all inherit the weaknesses of Bene that were cited above in the anticipation rejection, i.e., that Bene does not have the claimed connection point, and the first and second pumps of Bene do not pump said fluids to a catheter, but rather to a bubble trap. Although this alone should be reason enough to overcome the §103 rejections, further differences for each of the §103 rejections will be discussed separately.

A. Claims 5, 39 and 51 are rejected under 35 U.S.C. §103(a) as unpatentable over Bene et al. in view of Giles et al (PN 6,272,370).

The rejection cites Giles, saying:

> Giles et al. teaches that it is conventional in the art to utilize said

receiving step receives a fluid comprising blood and said pumping step pumps adenosine.

Giles et al. (hereinafter Giles) shows a device for targeted drug delivery (See Figure 1). A drug (8) is delivered to the subject by means of an osmotic pump (7). Giles states, in describing the method by which the drug may be delivered that,

> The method of the invention can be used within a wide range of medical procedures as in, for example...b) for catheter-based administration of thrombolytic agents, MR-visible contrast media, or cerebroprotective anti-ischemia drugs, such as ... adenosine agonists and antagonists. [1]

It is submitted that Giles does not teach a receiving step that receives a fluid comprising blood, but rather teaches a receiving step that comprises a fluid comprising a drug such as adenosine and a pumping step that pumps said drug. A combination of Bene and Giles would not form the presently claimed invention recited in claims 5, 39, and 51. Instead, a combination of Bene and Giles would result in a device which administers adenosine directly to the targeted area without first mixing with the subject's blood at a connection point. Therefore, the present invention as recited in claims 5, 39, and 51 are not obvious.

B. Claims 8, 12, 29, 32, 43-44 and 56 are rejected under 35 U.S.C. §103(a) as unpatentable over Bene et al. in view of Hogard et al (PN 6,284,131).

The rejection cites Hogard et al. saying

> Hogard et al. teaches that it is conventional in the art to utilize the fluids are delivered at a controlled temperature and pressure; comprising a temperature controller, configurable to provide heating or cooling to fluids in at least one of said first delivery tube and said second delivery line without contaminating the fluids; passing at least one of the fluids through a heat exchanger whereby at least one of the fluids is brought to a desired temperature prior to delivery to said catheter.

[1] Giles, column 23, lines 51-60

All limitations of the claimed invention must be considered when determining patentability. *In re* Lowry, 32 F.3d 1579, 1582, 32 U.S.P.Q.2d 1031, 1034 (Fed. Cir. 1994). In comparing Bene and Hogard to the claimed invention to determine obviousness, limitations of the presently claimed invention may not be ignored. Neither Bene nor Hogard teaches the claimed elements recited in independent claim 1, 25, and 42 of the present invention. Specifically, the defects of the rejections citing Bene have been pointed out above. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *See In re Fine,* 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); MPEP 2143.03. Therefore claims 8, 12, 29, 32, 43-44, and 56 are nonobvious.

C. Claims 11 and 58 are rejected under 35 U.S.C. §103(a) as unpatentable over Bene et al.

The rejection cites Bene, saying

> "Bene et al. teaches that it is conventional in the art to utilize the first delivery line contains a three-way check valve to prevent retrograde flow."

We submit that Bene does not teach that it is conventional in the art to utilize a check valve in the first delivery line in order to prevent retrograde flow. Bene states, in describing the blocking means shown in Fig. 1 (15),

> "...[B]locking means for either isolating the source or enabling the substitution/dialysis liquid to flow out into the circuit for extracorporeal blood circulation, or else for allowing the substitution/dialysis liquid to flow into the second compartment of the exchanger."

Referring to Fig. 1 of Bene, the end of the duct (13) not connected to the blocking means (15) terminates into the bubble trap (8). The bubble trap prevents retrograde flow, further providing evidence that the blocking means (15) does not prevent retrograde flow. Because the blocking means disclosed in Bene does not prevent retrograde flow, nor does Bene teach that such a device should be implemented, it would not have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a check valve in the second delivery line in order to prevent retrograde flow.

D. Claims 14, 33, and 45 are rejected under 35 U.S.C. §103(a) as unpatentable over Bene et al in view of Collins et al. (PN 6,303,036).

The rejection states,

> "Bene et al. teaches that it is conventional in the art to utilize a monitor to detect the temperature or blood pressure of a patient coupled to said pumping system. Collins et al. teaches that it is conventional in the art to utilize a monitor to detect the temperature or blood pressure of a patient coupled to said pumping system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized detecting the blood pressure of a patient since it would improve the effectiveness of the dialysis machine."

All limitations of the claimed invention must be considered when determining patentability. *In re* Lowry, 32 F.3d 1579, 1582, 32 U.S.P.Q.2d 1031, 1034 (Fed. Cir. 1994). In comparing Bene and Collins to the claimed invention to determine obviousness, limitations of the presently claimed invention may not be ignored. Neither Bene nor Collins teaches the claimed elements recited in independent claim 1, 25, and 42 of the present invention. Specifically, the defects of Bene have been pointed out above. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *See In re Fine,* 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); MPEP 2143.03. We therefore submit that dependent claims 14, 33, and 45 are nonobvious.

E. Claims 22, 41, and 54 are rejected under 35 U.S.C. §103(a) as unpatentable over Bene et al.

The rejection cites Bene, saying

> "Bene et al. discloses the second fluid is co-mingled with the first fluid a short distance from a target organ. Bene et al. does not disclose expressly the two fluids are co-mingled no further than twelve inches from a target organ. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to limit the co-mingling

distance to twelve inches because Applicant has not disclosed that limiting the co-mingling distance to twelve inches provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the standard distance taught by Bene et al. because it would provide adequate fluid transport."

We submit that it would not have been obvious matter of design choice to a person of ordinary skill in the art to limit the co-mingling distance to twelve inches and Applicants have disclosed that limiting the co-mingling distance to twelve inches provides an advantage and is used for a particular purpose. Applicants state,

"In the presently preferred embodiment, the junction (916) of delivery line (914) with (912) is no more than 12 inches from the target organ. This allows minimal time for the adenosine to be broken down by contact with the blood before it is delivered to the site where it is needed. In alternate embodiments, this maximum distance can be greater or less, depending on the particular components in the delivery lines and their reactivity with each other."[2]

Limiting the co-mingling distance to twelve inches as set forth in Claims 22, 41, and 54 would not be an obvious matter of design choice because the limit is specifically chosen with regard to certain criteria unique to the embodiment of the present invention. The maximum co-mingling distance is twelve inches when adenosine is to be mixed because its reactivity is such that it should not be mixed with blood until shortly before reaching the target organ. Given that the general reactivity of adenosine with blood and the approximate flow rate of an MPS system are known by those skilled in the art, the disclosure that the co-mingling distance is limited to twelve inches would serve to disclose to a person skilled in the art, the particular purpose and advantage of such a maximum co-mingling distance.

We further submit that one of ordinary skill in the art would not have expected the present invention to perform equally well given the disclosure in Bene related to the co-mingling distance. Bene does not disclose any teaching related to the co-mingling distance. Furthermore, Bene does not disclose the dimensions of the drawings showing

[2] Non-provisional Application No. 10/726,463, pg. 24, lines 23-28.

the system, nor that said drawings are to scale. When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. *See Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 U.S.P.Q.2d 1487, 1491 (Fed. Cir. 2000), MPEP 2125. Because Bene does not teach a maximum co-mingling distance, a co-mingling distance of twelve inches would not have been obvious to those skilled in the art at the time the invention was made.

F. Claims 24 and 53 are rejected under 35 U.S.C. §103(a) as unpatentable over Bene et al.

The rejection cites Bene, stating

> "Bene et al. discloses the claimed invention except for the multiple lumen. It would have been obvious to one having ordinary skill in the art at the same time the invention was made to increase the number of lumen, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 U.S.P.Q. 8."

We submit that the apparatus and method having a multiple lumen catheter as recited in claims 24 and 53 is not a mere duplication of essential working parts but rather an invention which produces a new and unexpected result. The duplication of essential working parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 671, 124 U.S.P.Q. 378 (CCPA 1960). The importance of minimizing the co-mingling distance has been discussed above. A catheter having multiple lumen produces the new and unexpected result off minimizing the co-mingling distance because the substances may enter the patient separately and not be mixed until just before injection into the target organ.[3] Nothing else in the Examiner's rejection suggests it would not have been obvious to one having ordinary skill in the art at the time the invention was made to increase the number of lumen in the catheter in order to minimize said co-mingling distance.

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[3] Non-provisional Application No. 10/726,463, pg. 25, lines 15-17.

Therefore, since neither Bene et al., nor the patents cited in combination with it, have shown the particular limitations of the claims discussed above, the rejections under 103 are asserted to be overcome.

CONCLUSION

It is respectfully urged that the subject application is patentable over the references cited by Examiner and is now in condition for allowance. Applicants request reconsideration of the application and allowance of the claims. If there are any outstanding issues that the Examiner feels may be resolved by way of a telephone conference, the Examiner is cordially invited to contact the undersigned attorney at 972.367.2001.

Respectfully submitted,

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